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APPLICATION NUMBER: *60/528,008*
FILING DATE: *December 09, 2003*
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Certified by

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EL969897984US

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
James N	CURTI	Bakersfield, CA

Additional inventors are being named on the 1 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (500 characters max)

RESPIRATORY THERAPY SYSTEM INCLUIDNG A NASAL CANNULA ASSEMBLY

Direct all correspondence to: **CORRESPONDENCE ADDRESS**

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 22
☑ Drawing(s) *Number of Sheets* 6
☐ Application Date Sheet. See 37 CFR 1.76
☐ CD(s), Number
☑ Other (specify) Express Mail Cert.
1pg Sub Formal Drawings
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SIGNATURE

Date December 9, 2003

REGISTRATION NO. 42,462 *(if appropriate)*

TYPED or PRINTED NAME Scott A. Daniels

Docket Number: SALTER PR47USP1

TELEPHONE 603-624-9220

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Docket Number SALTER PR47USP1

INVENTOR(S)/APPLICANT(S)

Given Name (first and middle [if any])	Family or Surname	Residence (City and either State or Foreign Country)
Peter W	SALTER	Tehachapi, CA
James M	DAVENPORT	Fallbrook, CA

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Application No.	
Filing Date	
First Named Inventor	James N. CURTI
Examiner Name	
Group Art Unit	
Attorney Docket No.	SALTER PR47USP1

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1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provision filing fee	$160
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2. CLAIMS

		Extra	Fee From Below		Fee Paid
Total Claims	44-20*	=22	$18 ($9)	x	=-0-
Ind. Claims	8- 3	=5	$86 ($43)	x	=-0-
Mult.Ind.Claims		=	$290 ($145)	x	=

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1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim
1204	86	2204	43	**Reissue independent claims over original patent
1205	18	2205	9	**Reissue claims in excess of 20 and over original patent
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1051	130	2051	65	Surcharge-late filing fee/oath	
1052	50	2052	25	Surcharge-late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for re-examination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Ext.for reply w/in 1 mon	
1252	420	2252	210	Ext.for reply w/in 2 mon	
1253	950	2253	475	Ext.for reply w/in 3 mon	
1254	1,480	2254	740	Ext.for reply w/in 4 mon	
1255	2,010	2255	1,005	Ext.for reply w/in 5 mon	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a Brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (for reissue)	
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1503	640	2503	320	Plant issue fee	
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1806	180	1806	180	Submission of Info.Disclo.Stmt.	
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1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
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1801	770	2801	385	Request for Cont.Exam. (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

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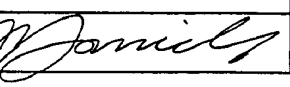
SUBMITTED BY

			Completed *(if applicable)*	
Typed or Printed Name	Scott A. Daniels	Registration Number	42,462	Telephone No. (603) 624-9220
Signature		Date: December 9, 2003	Deposit Account User ID	04-0213

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	James N. CURTI, Peter W. SALTER and James M. DAVENPORT
For	:	RESPIRATORY THERAPY SYSTEM INCLUDING A NASAL CANNULA ASSEMBLY
Docket	:	SALTER PR47USP1

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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	James N. CURTI, Peter W. SALTER and James M. DAVENPORT
Serial no.	:	
Filed	:	
For	:	RESPIRATORY THERAPY SYSTEM INCLUDING A NASAL CANNULA ASSEMBLY
Group Art Unit	:	
Examiner	:	
Docket	:	SALTER PR47US

The Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

SUBMISSION OF FORMAL DRAWINGS

Enclosed please find six (6) sheets of formal drawings which are to be entered in this case.

In the event that there are any fee deficiencies or additional fees are payable, please charge the same or credit any overpayment to our Deposit Account (Account No. 04-0213).

Respectfully submitted,

Scott A. Daniels, Reg. No. 42,462
Customer No. 020210
Davis & Bujold, P.L.L.C.
Fourth Floor
500 North Commercial Street
Manchester NH 03101-1151
Telephone 603-624-9220
Facsimile 603-624-9229
E-mail: patent@davisandbujold.com

[001] # RESPIRATORY THERAPY SYSTEM INCLUDING A NASAL CANNULA ASSEMBLY

This Application is a continuation-in-part of provisional application 60/490,577 filed July 28, 2003.

[002] ## FIELD OF THE INVENTION

[003] The present invention relates in general to respiratory assistance equipment and in particular to a respiratory therapy system including a nasal cannula assembly for use in the administration of fluids such as oxygen into the nasal passages of a person having respiratory ailments.

[004] ## BACKGROUND OF THE INVENTION

[005] A variety of flexible cannulas have been produced that are positioned to contact the nasal-labial area between the patient's upper lip and nostrils. Even though many of these cannulas were made of soft, flexible plastic, the wearer frequently encountered discomfort because a cannula is usually worn for a prolonged period of time. This results in continued contact of the cannula with the wearer's facial tissues, especially at the philtrum and around the unprotected nasal-labial area, thereby causing irritation and inflammation.

[006] The structures of conventional cannula devices may be categorized into two general groups.

[007] The first group utilizes a unitary member that includes a main tubular portion and a pair of tubular nasal prongs integrally connected to and in fluid communication with the main tubular portion. The main tubular portion has opposite ends which are connectable to flexible auxiliary oxygen supply tubes that are looped over the patient's ears and which themselves are in fluid communication with a pressurized source of oxygen. As is known, the nasal prongs are inserted into the nares of the wearer to deliver a low flow of oxygen to the patient's respiratory tract. The main tubular portion of these devices spans much if not all of the length of a wearer's upper lip. In so doing, the main tubular portion exerts contact pressure across much of the patient's upper lip. Under these circumstances, a patient usually begins to experience discomfort in a relatively short period of time even if the cannula itself and the auxiliary oxygen

supply tubes connected thereto are designed to deliver relatively low flows of oxygen, i.e., they not particularly robust, stiff or heavy in weight. Examples of cannula devices and assemblies constructed in accordance with this first group may be found in U. S. Patent Nos. 2,868,199; 3,643,660; 3,802,431; 4,106,505; 4,156,426; 5,400,776 and 5,794,619 and in published United States Patent Application Publications Nos. US 2001/0031929 A1 and US 2002/0112730 A1.

[008] The second group involves a harness member that does not itself convey oxygen but which retains flexible auxiliary oxygen supply tubes in such a way that their discharge outlet ends define nasal prongs. However, the harness members of these devices also typically span all or most of the length of a patent's upper lip whereby the devices, even in light-duty gas delivery environments, produce the same patient discomfort problems as the cannula devices of the first group. Examples of cannula devices constructed according to the second group may be found in U.S. Patent Nos. 2,931,358; 3,400,714; 4,278,082; 4,648,398; 4,790,308; 4,818,320 and 5,533,506.

[009] Published United States Patent Application Publication No. US 2002/0046755 A1 (the "`755 publication") discloses various embodiments of nasal cannulas that fall into one or the other of the aforementioned groups, as well as other embodiments that are not as readily classifiable. However, none of the nasal cannulas disclosed in that publication describe a device that would be comfortable to a patient under the high flow conditions a patient would experience under positive airway pressure therapy, e.g., continuous positive airway pressure (CPAP) or bilevel positive airway pressure (BiPAP), that is often prescribed to patients suffering from Obstructive Sleep Apnea Syndrome (OSAS), Chronic Obstructive Pulmonary Disorder (COPD) and other respiratory disorders. For example, according to one embodiment of cannula taught in the `755 publication, a relatively narrow connector member that would rest against a patient's upper lip is integrally attached to the flexible auxiliary oxygen supply tubes whereby the ends of the tubes would function as nasal prongs that elastically engage the user's nasal septum inside of the nostrils. As used herein the term "nasal septum" or, simply "septum" means the wall that divides the nasal cavity into halves which terminate

at the nostrils. At its front or anterior portion the septum is a firm but bendable structure made mostly of cartilage that is covered by skin. In order to deliver the 15+ liters per minute respiratory gas flow to a cannula that would be therapeutically desirable to maintain a typical adult patient's respiratory passageways open during OSAS, for example, conventional auxiliary oxygen supply tubes must have an outer diameter of up to about 1/4". Tubes of this caliber, when inserted short distances into the nostrils (as they must be so as not to harm internal nasal tissues), would be quite obtrusive, stiff and uncomfortable to the user, especially when in elastic contact with the user's septum. Such discomfort would,, in turn, detrimentally impact the patient's compliance with his or her prescribed positive airway pressure regime and, therefore, reduce the overall effectiveness of therapy.

[010] U.S. Patent Nos. 4,782, 832; 5,042,478; 5,134,995; 5,269,296; 5,535,739; 5,687,715; 5,752,510; 6,431,172 and 6,478,026, as well as published United States Patent Application Publication No. US 2002/005935 A1, described nasal cannulas for positive airway pressure therapy. However, the cannula devices disclosed in these documents are quite large and cumbersome. Indeed, many are designed to cover and/or seal the patient's nostrils. Consequently, they too are not conducive to optimum patient therapy compliance.

[011] An advantage exists, therefore for respiratory therapy system including a nasal cannula assembly that is compact, lightweight and fabricated from highly flexible material. So constructed, the assembly would be comfortable to patients that undergo respiratory therapy involving the administration of pressurized respiratory gases for extended periods of time, including therapy involving the administration of pressurized respiratory gases at the high flow rates that are useful in positive airway pressure therapy.

[012] SUMMARY OF THE INVENTION

[013] The present invention provides a respiratory therapy system including a nasal cannular assembly adapted to contact the nasal-labial area of a patient's face. The cannula assembly comprises a nasal cannula, a pair of flexible auxiliary respiratory gas supply tubes connected to the nasal cannula, a main respiratory

gas supply line and, preferably a slip loop disposed about the auxiliary supply tubes.

[014] The nasal cannula is a unitary member desirably made of a highly flexible or pliable material. The cannula is molded so as to define a narrow central member and a pair of flexible tubular arms integrally formed along opposite edges of the central member that are connectable to pair of auxiliary respiratory gas supply tubes. The inner ends of the tubular arms define a pair of spaced-apart hollow tubular extensions or prongs projecting upwardly in a curved configuration from the central member. The tubular extensions are inserted into the nostrils of the wearer and their curved configuration permits a positive guiding of the respiratory gas supply along the natural contours of the nasal passages into the pharynx.

[015] The upper surface of the central member is preferably rounded in order to minimize the area of contact on the lower, outer surface of the nasal septum and to avoid any straight edges that would concentrate pressure against the septum. This, coupled with the inherent flexibility and short length of the central member allows the cannula to lightly contact a small portion of the nasal-labial area of the patient.

[016] In addition, the flexible tubular arms of the cannula are designed such that, when they are connected to the auxiliary respiratory gas supply tubes and the cannula assembly is properly donned by the patient, the arms flex in such a way as to urge the auxiliary respiratory gas supply tubes to pass under rather than across or above the patient's cheekbones. The advantage of this effect is that it avoids the discomfort that some patients experience when nasal cannula auxiliary respiratory gas supply tubes contact the tissues of their cheekbone structures. Thus, when the nasal cannula assembly of the present invention is subjected to the pulling force of the auxiliary respiratory gas supply tubes when the assembly is worn by a patient, it exerts minimal pressure against both the patient's nasal-labial and cheekbone tissue areas. In addition, it provides positive positioning of the tubular extensions within the nasal passages while spacing their surfaces from the interior walls of the nasal passages, including the septum. The

result is a highly comfortable assembly that can be worn by a patient for long periods of time even under conditions of high gas flow rates whereby the patient is more likely to comply with and obtain the optimum benefits of his or her respiratory therapy regime.

[017] Other details, objects and advantages of the present invention will become apparent as the following description of the presently preferred embodiments and presently preferred methods of practicing the invention proceeds.

[018] BRIEF DESCRIPTION OF THE DRAWINGS

[019] The invention will become more readily apparent form the following description of preferred embodiments thereof shown, by way of example only, in the accompanying drawings where:

[020] Fig. 1 is an enlarged elevational view of a portion of a cannula assembly according to the present invention in operative position on a patient;

[021] Fig. 2 is an elevational view of a complete cannula assembly according to the present invention in operative position on a patient;

[022] Fig. 3 is a rear elevational view of the cannula of the cannula assembly according to the present invention;

[023] Fig. 4 is an enlarged cross-sectional view taken along line 4-4 of Fig. 3 showing the relative position of the cannula of Fig. 3 when secured to a patient with its extensions inserted into the patent's nasal cavity;

[024] Fig. 5 is a top plan view of the cannula of Fig. 3;

[025] Fig. 6 is a block diagram of a respiratory therapy system including a nasal cannula assembly according to the present invention; and

[026] Fig. 7 is a diagrammatic view of another embodiment of the respiratory therapy system.

[027] Fig. 8 is a block diagram of another embodiment of a respiratory therapy system including a nasal cannula assembly according to the present invention

[028] DETAILED DESCRIPTION OF THE INVENTION

[029] Referring to the drawings wherein like or similar references indicate like or similar elements throughout the several view, there is shown in Figs. 1 and 2 a cannula assembly according to the present invention in operative position on a patient's face and generally designated by reference numeral 10. As illustrated more completely in Fig. 2, assembly 10 comprises a nasal cannula 12, a pair of auxiliary respiratory gas supply tubes 14 connected to tubular arms 26 of the cannula (described below), a main respiratory gas supply line 16, a connector 18 for joining auxiliary tubes 14 to supply tube 16, an optional slip loop 20 disposed about auxiliary tubes 14 to adjust the first of the auxiliary tubes about the patient's ears and head, and a connector 22 for connecting the main respiratory gas supply line 18 to a source of pressurized respiratory gas 23. As set forth in greater detail in connection with the description of Fig. 6, pressurized respiratory gas source 23 may comprise a pressurized cylinder of oxygen or other supply of therapeutic gas and/or a compressor for delivering pressurized air (such as is commonly used in the treatment of OSAS and other respiratory disorders utilizing the administration of positive pressure to a patient's airway). Depending on a patient's therapeutic needs, a respiratory therapy system including pressurized respiratory gas source 3 may deliver heated or unheated as well as humidified or dry respiratory gas to a patient.

[030] Cannula 12 is a unitary member that may be fabricated by any suitable molding process such as, for example, a dip molding process. Examples of dip molding processes for cannula formation include those disclosed in United States Patent Application Serial Nos. 09/754,471 and 09/883,843 (both of which are entitled "Method to Produce Nasal and Oral Cannula Breathing Detection Devices"), the disclosures of which are incorporated herein in their entireties by reference thereto. The composition of cannula 12 is preferably a thermoplastic composition such as polyvinyl chloride, polyvinyl acetate, polyethylene, soft latex or other materials that are highly pliable or flexible. As most clearly illustrated in Figs. 1, 3 and 5, cannula 12 comprises a narrow or short-length central member 24 and a pair of flexible tubular arms 26. First ends of the tubular arms 26 are

integrally connected to the central member 24 along opposite end edges 28 thereof (as shown in Fig. 3) and second ends of the tubular arms 26 are respectively connectable to the auxiliary respiratory gas supply tubes 14 (as shown in Figs. 1 and 2). The connection between arms 26 of cannula 12 and auxiliary respiratory gas supply tubes 14 may be effectuated by any suitable method or means and the connection may be releasable or permanent. For example, according to a presently preferred embodiment, tubular arms 26 closely receive the auxiliary respiratory gas supply tubes 14 and their connections may be maintained by friction fit solvent or adhesive bonding, ultrasonic welding or the like.

[031] As shown in Figs. 4 and 5, a pair of spaced-apart hollow tubular extensions, nozzles or prongs 30 are integrally formed with and project upwardly from the first ends of the tubular arms 26. Tubular extensions 30 preferably assume a curved configuration corresponding substantially to that of the anterior regions of a patient's nasal cavity and terminate at respiratory gas discharge outlets 32. For optimum patient comfort, tubular extensions 30 preferably taper upwardly from the top of the central member 24 to discharge outlets 32. In operation, tubular extensions 30 are inserted into the nostrils of the wearer and they extend into the nasal cavity N. Their curved configuration permits a positive guiding of the respiratory gas supply along the natural contours of the nasal passages into the pharynx P rather than the upper reaches of the nasal cavity where it would cause pressure and potentially irritate the patient. In addition, there are no sharp edge openings at the tips of the extensions 30 to irritate the nasal passage due to the continued movements of breathing and the soft, flexible material of the cannular permits the extensions to easily conform to the contours of the nasal cavity N.

[032] Unlike some conventional nasal cannulas that possess structure which spans most if not all of a patient's upper lip, the central member 24 of cannula 12 is quite narrow or short in length. Indeed, it is configured to span substantially no more than the width of the patient's philtrum 34 (Fig. 1). As a result, a minimal area of the front surface of the patient's upper lip is in continuous on tact with the cannula 12 during operation. Additionally, as shown in Fig. 4, the upper surface of central member 24 is preferably rounded in order to minimize the area of contact

on the lower, outer surface of the nasal septum and to avoid any straight edges that would concentrate pressure thereagainst. Thus, the combination of these features causes the cannula 12 to lightly contact a small portion of the nasal-labial area of the patient, thereby enhancing both the comfort of patients who must wear a nasal cannula for prolonged periods of time and their willingness to comply their respiratory therapy programs.

[033] Referring again to Figs. 1 and 2, these figures illustrate the preferred manner in which the cannula assembly 10 is to be worn by a patient. The cannula 12 rests generally across the patient's nasal-labial area while the flexible auxiliary respiratory gas supply tubes 14 are directed across the patient's face, over and behind the ears, down the haw areas and brought together under the chin. Slip loop 20, which is of sufficient size to encompass both auxiliary supply tubes 14, may then be adjusted so that the cannula 12 will remain firmly in place without the tubes being uncomfortably taut.

[034] As depicted in Fig. 5, according to a presently preferred construction, the central member 24 of cannula 12 has a horizontal axis X extending along its length. Each of the tubular arms 26 has an X'-axis extending along its length that extends rearwardly at an acute angle α to the horizontal axis X of the central member 24. Disposing arms 26 at a rearward angle α with respect to central member 24 serves to minimize the amount of tension that must be applied to the auxiliary respiratory gas supply tubes 14 to keep the cannula in position against the patient's nasal-labial area and thus the force that the central member 24 applies to that area.

[035] Additionally, as shown in Fig. 3, the tubular arms 26 at each end of the central member 24 extend downwardly and outwardly from their first ends to their second ends in a gently curved configuration having a radius of curvature of about 0.4 inch to about 0.8 inch depending on the facial characteristics and head size of the patient that will use the device, e.g., child or adult. Although arms 26 are highly flexible and yieldable they nevertheless possess sufficient resilience or stiffness to impart a desirable configuration to the auxiliary supply tubes 14 which

further enhances the patient's comfort. That is, the curved tubular arms 26 function to urge the auxiliary respiratory gas supply tubes 14 to pass beneath rather than across or over the patient's cheekbone areas 36 (Fig. 1). The advantage of this effect is that it avoids the discomfort that some patients experience when nasal cannula auxiliary respiratory gas supply tubes contact their cheekbone areas. Thus, when the nasal cannula assembly 10 of the present invention is subjected to the pulling force of the auxiliary respiratory gas supply tubes 14 when the assembly is worn by a patient (which pulling force is greater for larger caliber and stiffer auxiliary respiratory gas supply tubes that are designed to deliver high respiratory gas flows), it exerts minimal pressure against both the patient's nasal-labial and cheekbone areas.

[036] As mentioned hereinabove, the cannula assembly of the present invention is designed such that it will find beneficial application whether it is used to convey respiratory gases under low flow rates such as might be administered in oxygen assistance therapy or high flow rates of at least about 15 liters per minute per nostril as might be required for positive airway pressure administration for treatment of OSAS, COPD and the like. In any event, however, for a particular therapy regime, the dimensions of main respiratory gas supply line 16, auxiliary respiratory gas supply lines 14 and cannula tubular arms 26 will be optimized to provide minimum bulk and weight, minimal pressure drop, maximum flow and minimum turbulence and noise. In addition, it will be understood that the nasal cannula 12 may be molded to any dimensions suitable to accommodate the particular physical facial characteristics and sizes of patents ranging in size from very small children to very large adults. The result is a highly comfortable assembly that can be worn by a patient for long periods of time even under conditions of high gas flow rates whereby the patient is more likely to comply with and obtain the optimum benefits of his or her respiratory therapy regime.

[037] Fig. 6 illustrates, in general, a respiratory therapy system 40 including a pressurized respiratory gas source 23 for supplying the respiratory gas to the system 40 and the patient P, and a nasal cannula assembly 10 according to the present invention. The respiratory therapy system 40, described in further detail

below, can be generally defined as an open system providing a high-flow of respiratory gas to the patient P. An open system is generally substantially open to the effects of ambient air pressure. As is readily apparent to one skilled in the art, this occurs at the opening 32 of the nasal cannula assembly 10 where the respiratory gas flow is introduced into the nares of the patient's nose.

[038] In contrast to the open respiratory therapy system 40 of present invention, the previously known sleep apnea gas delivery systems are, in general, closed systems, providing respiratory gas at a specified higher pressure relative to the ambient air pressure. In such closed systems, a face mask is sealed over the mouth and nose of the patient P, thus creating the closed pressure system. A closed gas delivery system may provide pressures in the range of 4 to 20 cm H_2O in the patient's respiratory passages to maintain an open airway. This closed system and the sealed mask are, of course, worn by the patient while they are sleeping, however, the sealed mask and the pressure developed thereby with the delivered respiratory gas are particularly uncomfortable to the patient and the treatment is often abandoned by the patient after several sessions.

[039] In many cases of sleep apnea, the burden and effect of such closed systems is not necessary. The open respiratory therapy system 40 of the present invention overcomes the above noted drawbacks of known closed therapy systems. The above described nasal cannula assembly 10 is substantially more comfortable for the patient then the masks used in known sleep apnea treating systems. Thus, the patient is less apt to remove the mask and forego the therapy based on a discomfort factor. Also, the high flow, low pressure or ambient atmospheric pressure of the open system also lessens the discomfort factor of the patient's respiratory system being substantially continuously pressurized. The delivery of a high flow of respiratory gas to the patient's airways ensures that there is an abundance of the respiratory gas available to the patient at about atmospheric or slightly greater than atmospheric pressure.

[040] In general, as shown by the heavy black arrows of Fig. 6 as well as in Fig. 7, the respiratory therapy system 40 of the present invention supplies gas from a source 42 to an initial gas flow developing means 44 for imparting a high desired

flow rate of the respiratory gas through the remainder of the system 40 and out of the nasal cannula 10 and into the patient's upper respiratory system. The high flow rate permits the patients lungs to freely draw in the respiratory gas, and the high flow rate of respiratory gas provides a rich , abundant supply of the treating respiratory gas without the need for developing a significant over pressure in the patient's lungs by using a sealing mask covering the patient's mouth and nose. The flow developing means 44 for developing the desired flow rate can be a compressor, fan, pump, blower or the like as known in the art. Preferably in the present invention, a compressed gas supply (compressor) capable of providing from 0 to 100 lpm at pressures of from between 0 and 5 psi, for developing the desired flow rate is utilized.

[041] The flow of respiratory gas must also be conditioned. At least a heating means 48 and a humidifying means 50 are provided to condition the respiratory gas. The therapeutic gas must be warm and most in order to avoid patient discomfort and harm tot eh tissues of the patient's nasal cavity. In particular, respiratory gas supplied at the above described flow rates should be maintained at a relative humidity of about 50 percent and 100 percent and more preferably at about 85 percent. Additionally, the temperature of the supplied gas should be within the range of about 80 degrees and 95 degrees and preferably about 86 degrees.

[042] High flow conditions may also tend to create noise and turbulence in the auxiliary gas supply lines which causes discomfort to the patient and can be detrimental to the patient's long term use of the system. Besides, the previously described nasal cannula 10, the auxiliary respiratory gas supply lines 14 sufficient to satisfy the above ga delivery conditions and minimize size, bulk, weight, turbulence and noise, may have an inner diameter of about .173 or 3/16 inch include and an outer diameter of about .225 or 7/32 inch, although other sizes are also contemplated as well as ribbon supply lines may be used as well to prevent kinking of the supply lines.

[043] In the case of a specially prepared therapeutic gas supply, to conserve the therapeutic gas supply 42, a check valve 46 or other suitable supply gas metering

means 46 is preferably provided as part of the respiratory gas source 42. The therapeutic gas is thus supplied via the metering means 46 to the flow developing means 44. Following the flow developing means 44, the gas may be supplied to the humidifying means 50 to humidify the gas and the heating means 47 before being finally supplied through the cannula assembly to the patient P.

[044] A controller 56 is used to monitor the desired flow, as selected by the user, or as required by the ramp or hot start functions.

[045] Said controller provides means to increase flow from about 0 to 100 lpm over a period of from about 5 minutes to 1 hour, to enable the patient to acclimate to the desired flow rate (ramp function). This ramp function can be used for both initial cold startups and hot interrupted sleep starts

[046] Additionally, a controller 56 continuously monitors the respiratory gas temperature and provides an input to the humidifying means 50 and the heating means 48 to control the respective gas, humidity and temperature. Controller 56 also monitors and provides control of humidity and temperature throughout the ramp functions so as to maximize patient comfort. The controller 56 is provided with control logic circuits to monitor and control these various aspects of the respiratory therapy system 40 and as such control logic circuits are well known in the art, no further discussion is provided.

[047] A number of other devices may also be provided to supply different inputs to the controller. For example, an ambient temperature sensor 66 may supply the ambient temperature to the controller 56 to optimize the humidity and temperature levels in the gas relative to the patient's ambient temperature surroundings. Also, the system 40 may include an ambient humidity sensor 67 for sensing the ambient humidity and more effectively controlling the humidity of the respiratory gas leaving the heated reservoir 50.

[048] In a still further embodiment of the present invention as shown in Fig. 8, the respiratory therapy system 40 may provide the gas, either before or after passing through a flow developing means 44, through a humidifier 70, , for example, a pass over humidifier or other type of humidifier known in the art provided with

variable heat control to more efficiently manage humidification and increase water vapor in the gas. The humidified gas is next sent to a heating means 48 and passed to the cannula 10 for supply to the patient P. Again, as discussed above, the controller 56 is used to monitor and control the system components, namely the flow development means 44, humidifier 70 and the heating means 48. A temperature sensing means 58 may be provided in the system 40 after the heating means 48, and an ambient room temperature sensing means 66 and ambient room humidity sensing means 67 may be provided as inputs to the controller 56 which ensures respiratory gas is controlled at a level necessary for the patient P.

[049] Since certain changes may be made in the above described respiratory therapy system without departing form the spirit and scope of the invention herein involved, it is intended that all of the subject matter of the above description or shown in the accompanying drawings shall be interpreted merely as examples illustrating the inventive concept herein and shall not be construed as limiting the invention.

CLAIMS

What is claimed is:

1. A unitary nasal cannula comprising:

a central member having a length substantially no greater than the width of a patient's philtrum;

a pair of tubular arms having first ends integrally connected to said central member and second ends that are connectable to auxiliary respiratory gas supply tubes of a nasal cannula assembly; and

tubular extensions formed integrally with said first ends of said tubular arms, said tubular extensions being adapted for insertion into a patient's nostrils and terminating at respiratory gas discharge outlets.

2. The nasal cannula of claim 1 wherein said tubular extensions are curved.

3. The nasal cannula of claim 2 wherein said tubular extensions taper upwardly from said central member to said discharge outlets.

4. The nasal cannula of claim 1 wherein said nasal cannula is composed entirely of a flexible material.

5. The nasal cannula of claim 1 wherein said tubular arms extend downwardly and outwardly from their first ends to their second ends in a curved configuration, whereby said tubular possess stiffness sufficient to urge the auxiliary respiratory gas supply tubes of a nasal cannula assembly to pass beneath a patient's cheekbone areas when the nasal cannula is connected to the auxiliary respiratory gas supply tubes of a nasal cannula assembly and the nasal cannula assembly is donned by a patient.

6. The nasal cannula of claim 4 wherein said tubular arms extend downwardly and outwardly from their first ends to their second ends in a curved configuration, whereby said tubular possess stiffness sufficient to urge the auxiliary respiratory gas supply tubes of a nasal cannula assembly to pass beneath a patient's cheekbone areas when the nasal cannula is connected to the auxiliary respiratory gas supply tubes of a nasal cannula assembly and the nasal cannula assembly is donned by a patient.

7. A nasal cannula assembly comprising:

a main respiratory gas supply line;

a pair of auxiliary respiratory gas supply tubes connected to said main respiratory gas supply line; and

a unitary nasal cannula connected to said auxiliary respiratory gas supply tubes, said nasal cannula comprising:

a central member having a length substantially no greater than the width of a patient's philtrum;

a pair of tubular arms having first ends integrally connected to said central member and second ends connected to said auxiliary respiratory gas supply tubes; and

tubular extensions formed integrally with said first ends of said tubular arms, said tubular extensions being adapted for insertion into a patient's nostrils and terminating at respiratory gas discharge outlets.

8. The nasal cannula assembly of claim 7 wherein said tubular extensions are curved.

9. The nasal cannula assembly of claim 8 wherein said tubular extensions taper upwardly from said central member to said discharge outlets.

10. The nasal cannula assembly of claim 7 wherein said nasal cannula is composed entirely of a flexible material.

11. The nasal cannula assembly of claim 7 wherein said tubular arms extend downwardly and outwardly from their first ends to their second ends in a curved configuration, whereby said tubular arms possess stiffness sufficient to urge said auxiliary respiratory gas supply tubes to pass beneath a patient's cheekbone areas when the nasal cannula assembly is donned by a patient.

12. The nasal cannula assembly of claim 10 wherein said tubular arms extend downwardly and outwardly from their first ends to their second ends in a curved configuration, whereby said tubular arms possess stiffness sufficient to urge said auxiliary respiratory gas supply tubes to pass beneath a patient's cheekbone areas when the nasal cannula assembly is donned by patient.

13. A respiratory therapy system comprising:

a nasal cannula assembly including amain respiratory gas supply line, a pair of auxiliary respiratory gas supply tubes connected to said main respiratory gas supply line and a unitary nasal cannula connected to said auxiliary respiratory gas supply tubes, said nasal cannula being a separate component with respect to said auxiliary respiratory gas supply tubes; and

a source of pressurized respiratory gas connected to said main respiratory gas supply line for delivering pressurized respiratory gas to said main respiratory gas supply line.

14. The respiratory therapy system of claim 13 wherein said pressurized respiratory gas source includes means for providing at least one of therapeutic gas and pressurized air to said main respiratory gas supply line.

15. The respiratory therapy system of claim 13 further comprising means of heating pressurized respiratory gas delivered by said pressurized respiratory gas source to said main respiratory gas supply line.

16. The respiratory therapy system of claim 13 further comprising means for humidifying pressurized respiratory gas delivered by said pressurized respiratory gas source to said main respiratory gas supply line.

17. The respiratory therapy system of claim 15 further comprising means for humidifying pressurized respiratory gas delivered by said pressurized respiratory gas source to said main respiratory gas supply line.

18. The respiratory therapy system of claim 15 wherein each of said auxiliary respiratory gas supply tubes is dimensioned to deliver pressurized respiratory gas at a flow rate of at least about 15 liters per minute.

19. A respiratory therapy system comprising:

a nasal cannula assembly comprising

a main respiratory gas supply line;

a pair of auxiliary respiratory gas supply tubes connected to said main respiratory gas supply line; and

a unitary nasal cannula connected to said auxiliary respiratory gas supply tubes, said nasal cannula comprising:

a central member having first ends integrally connected to said central member and second ends connected to said auxiliary respiratory gas supply tubes; and

tubular extensions formed integrally with said first ends of said tubular arms, said tubular extensions being adapted for insertion into a patient's nostrils and terminating at respiratory gas discharge outlets; and

a source of pressurized respiratory gas connected to said main respiratory gas supply line for delivering pressurized respiratory gas to said main respiratory gas supply line.

20. The respiratory therapy system of claim 19 wherein said pressurized respiratory gas source includes means for providing at least one of therapeutic gas and pressurized air to said main respiratory gas supply line.

21. The respiratory therapy system of claim 20 further comprising means for heating pressurized respiratory gas delivered by said pressurized respiratory gas source to said main respiratory gas supply line.

22. The respiratory therapy system of claim 19 further comprising means for humidifying pressurized respiratory gas delivered by said pressurized respiratory gas source to said main respiratory gas supply line.

23. The respiratory therapy system of claim 21 further comprising means for humidifying pressurized respiratory gas delivered by said pressurized respiratory gas source to said main respiratory gas supply line.

24. The respiratory therapy system of claim 21 wherein each of said auxiliary respiratory gas supply tubes is dimensioned to deliver pressurized respiratory gas at a flow rate of at least about 15 liters per minute.

25. The respiratory therapy system of claim 19 wherein said tubular extensions are curved.

26. The respiratory therapy system of claim 25 wherein said tubular extensions taper upwardly from said central member to said discharge outlets.

27. The respiratory therapy system of claim 19 wherein said nasal cannula is composed entirely of a flexible material.

28. The respiratory therapy system of claim 19 wherein said tubular arms extend downwardly and outwardly from their first ends to their second ends in a curved configuration, whereby said tubular possess stiffness sufficient to urge the auxiliary respiratory gas supply tubes of a nasal cannula assembly to pass beneath a patient's cheekbone areas when the nasal cannula is connected to the auxiliary respiratory gas supply tubes of a nasal cannula assembly and the nasal cannula assembly is donned by a patient.

29. The respiratory therapy system of claim 27 wherein said tubular arms extend downwardly and outwardly from their first ends to their second ends in a curved configuration, whereby said tubular possess stiffness sufficient to urge the auxiliary respiratory gas supply tubes of a nasal cannula assembly to pass beneath a patient's cheekbone areas when the nasal cannula is connected to the auxiliary respiratory gas supply tubes of a nasal cannula assembly and the nasal cannula assembly is donned by a patient.

30. A method for providing respiratory therapy to a patient, said method comprising the steps of:

providing a nasal cannula assembly including a main respiratory gas supply line, a pair of auxiliary respiratory gas supply tubes connected to the main respiratory gas supply line and a unitary nasal cannula connected to the auxiliary respiratory gas supply tubes, the nasal cannula being a separate component with respect to the auxiliary respiratory gas supply tubes and having tubular extensions adapted for insertion into a patient's nostrils, the tubular extensions terminating at respiratory gas discharge outlets;

inserting the tubular extensions into a patient's nostrils; and

connecting a source of pressurized respiratory gas to said main respiratory gas supply line whereby pressurized respiratory gas is delivered to the main respiratory gas supply line, the auxiliary respiratory gas supply tubes and the nasal cannula and whereby the pressurized respiratory gas is discharged into each nostril of the patient at a flow rate of at least about 15 liters per minute through the each of the respiratory gas discharge outlets of the tubular extensions of the nasal cannula.

31. The method for providing respiratory therapy to a patient of claim 30 further comprising supply at least one of therapeutic gas and pressurized air to said main respiratory gas supply line from the pressurized respiratory gas source.

32. The method for providing respiratory therapy to a patient of claim 30 further comprising heating the pressurized respiratory gas delivered by the pressurized respiratory gas source to the main respiratory gas supply line.

33. The method for providing respiratory therapy to a patient of claim 30 further comprising humidifying the pressurized respiratory gas delivered by the pressurized respiratory gas source to the main respiratory gas supply line.

34. The method for providing respiratory therapy to a patient of claim 33 further comprising humidifying the pressurized respiratory gas delivered by the pressurized respiratory gas source to the main respiratory gas supply line.

35. A gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula, the gas delivery system comprising:

a gas supply for supplying the therapeutic treating gas for the gas delivery system;

a gas flow conditioning means for developing a desired flow rate and providing a desired temperature and humidity to the treating gas;

the nasal cannula having a first gas supply tube and a second gas supply tube connected by a flexible central bridge; and

wherein each of said first and second gas supply tubes are provided with a gas inlet and a gas outlet separated by a curved, flexible intermediate portion having sufficient resilience to maintain an arc between the gas inlet and the gas outlet of about 90 to 180 degrees.

36. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 35 wherein the arc of the intermediated portion separating the gas inlet and a gas outlet extends along a plane generally defined by the patients cheek contour between a nare on one side of the patients nose and an ear on a respective side of the patients head.

37. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 35 wherein the gas inlet on

the first gas supply tube is separated from the gas inlet of the second supply tube by an angle of less then 180 degrees.

38. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 37 wherein the gas outlet on the first gas supply tube and the outlet on the second gas supply tube are substantially parallel.

39. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 37 wherein the gas outlet on the first gas supply tube and the gas outlet on the second gas supply tube are substantially parallel and separated by the flexible central bridge about the width of a patient's philtrum.

40. A gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula, the gas delivery system comprising:

a gas supply for supplying the therapeutic treating gas for the delivery system;

a flow developing means, a humidifier and a heater for supplying conditioned therapeutic treating gas from the system to the patient at a flow rate of at least 1-5 liters/minute, a temperature of between about 80-95°F, and having a relative humidity of between about 50% to 100%; and

the nasal cannula having a first gas supply tube and a second gas supply tube connected by a flexible central bridge, each of said first and second gas supply tubes having a gas inlet and a gas outlet communicating along a curved, flexible intermediate portion having sufficient resilience to maintain an arc between the gas inlet and the gas outlet of about 90 to 180 degrees.

41. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 40 further comprising an electronic controller for maintaining the flow humidity and temperature of the conditioned treating gas.

42. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 41 further comprising at least

one of an ambient air temperature sensor input and an ambient air humidity sensor input to the controller.

43. The gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula as set forth in claim 40 wherein the flexible central bridge resiliently maintains the outlets of the relative first and second gas supply tubes substantially parallel, and maintains an angle between the respective inlets of the first and second gas supply tubes between about 40 to 100 degrees.

44. An open gas delivery system for delivering therapeutic treating gas to a patient through a nasal cannula, the gas delivery system comprising:

a gas supply for supplying the therapeutic treating gas for the gas delivery system;

a flow developing means, a humidifying means and a heating means for supplying conditioned therapeutic treating gas from the system to the patient at a flow rate of at least about 2 liters/minute per nostril, a temperature between about 80-95 °F, and having a relative humidity of between about 50% to 100%;

the nasal cannula having a first gas supply tube and a separate second gas supply tube connected by a flexible central bridge, each of said first and second gas supply tubes having a gas inlet and a gas outlet communicating along a curved, flexible intermediate portion having sufficient resilience to maintain an arc between the gas inlet and the gas outlet of between about 90 to 180 degrees; and

wherein the treating gas flow developed by the flow rate developing means and output to the patient via the nasal cannula is exposed to the effects of ambient air pressure.

ABSTRACT OF THE DISCLOSURE

A respiratory therapy system including a nasal cannula assembly. The cannula assembly includes a highly flexible nasal cannula adapted to contact the nasal-labial area of a patient's face. The cannula has a narrow central member and a pair of flexible tubular arms integrally formed along opposite edges of the central member that are connectable to pair of auxiliary respiratory gas supply tubes of the nasal cannula assembly. The inner ends of the tubular arms form a pair of spaced-apart hollow nasal prongs that project upwardly in a curved configuration from the central member. When the assembly is worn by a patient, it exerts minimal pressure against the both the patient's nasal-labial and cheekbone areas whereby a patient is more apt to comply with and obtain the optimum benefits of his or her respiratory therapy regime.

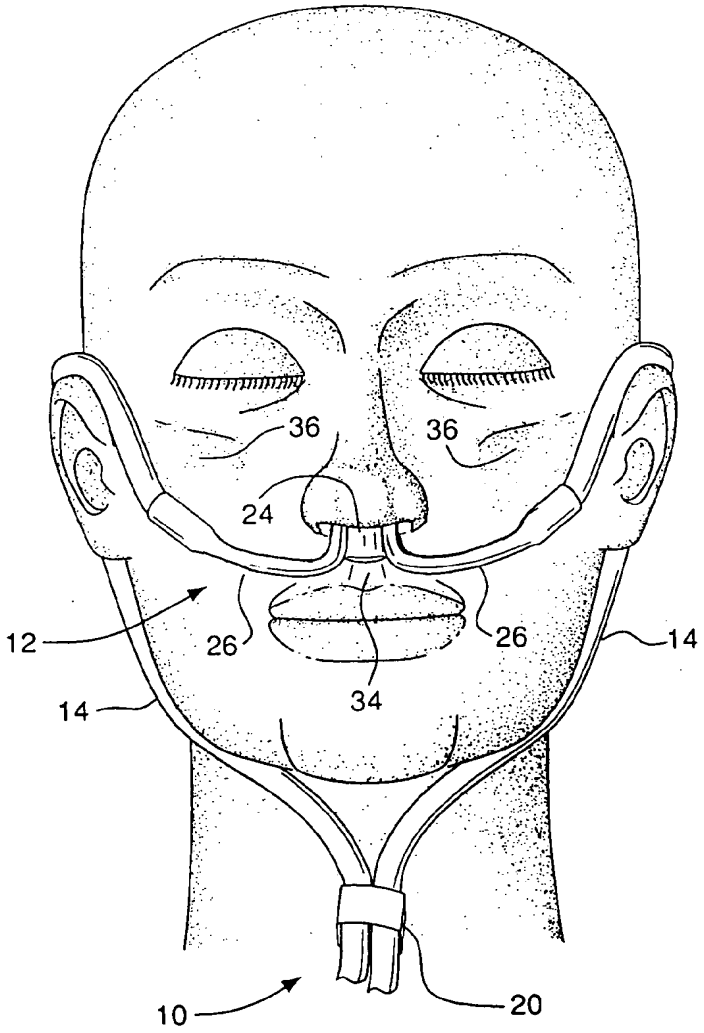

FIG. 1

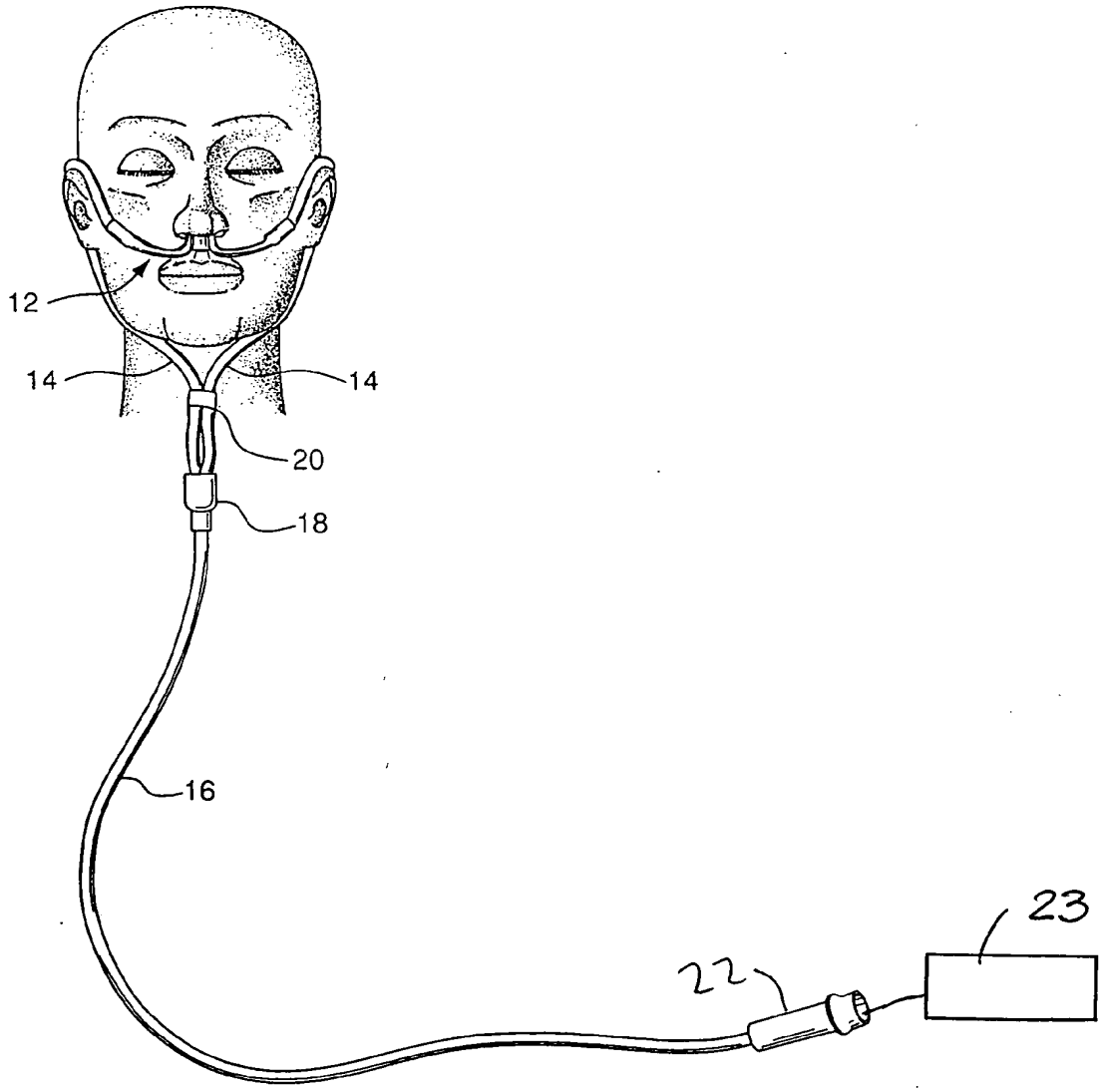

FIG. 2

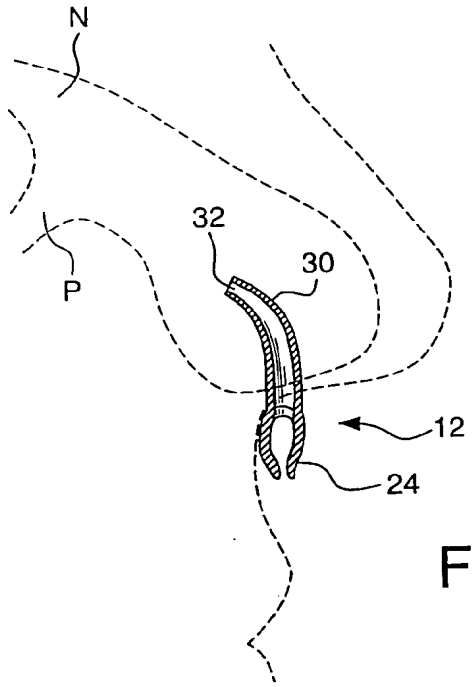

FIG. 4

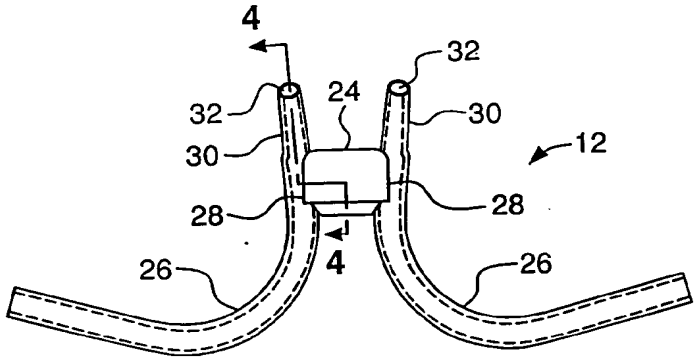

FIG. 3

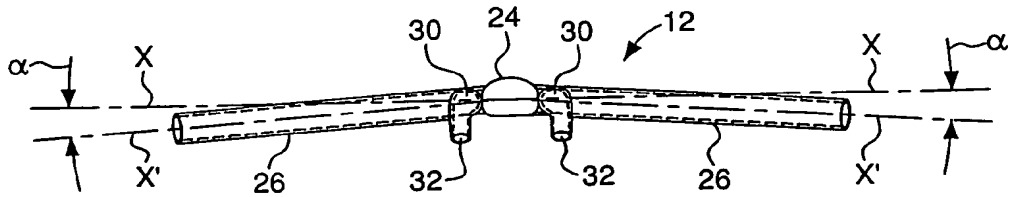

FIG. 5

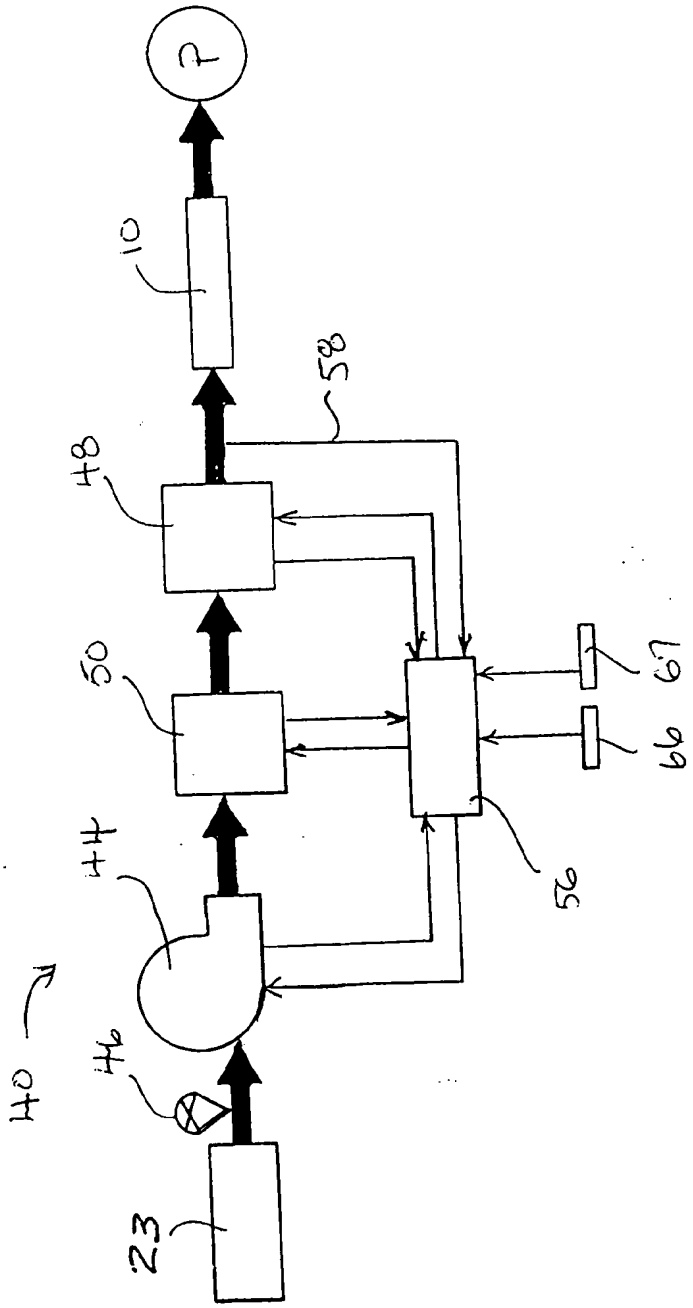

Fig. 6

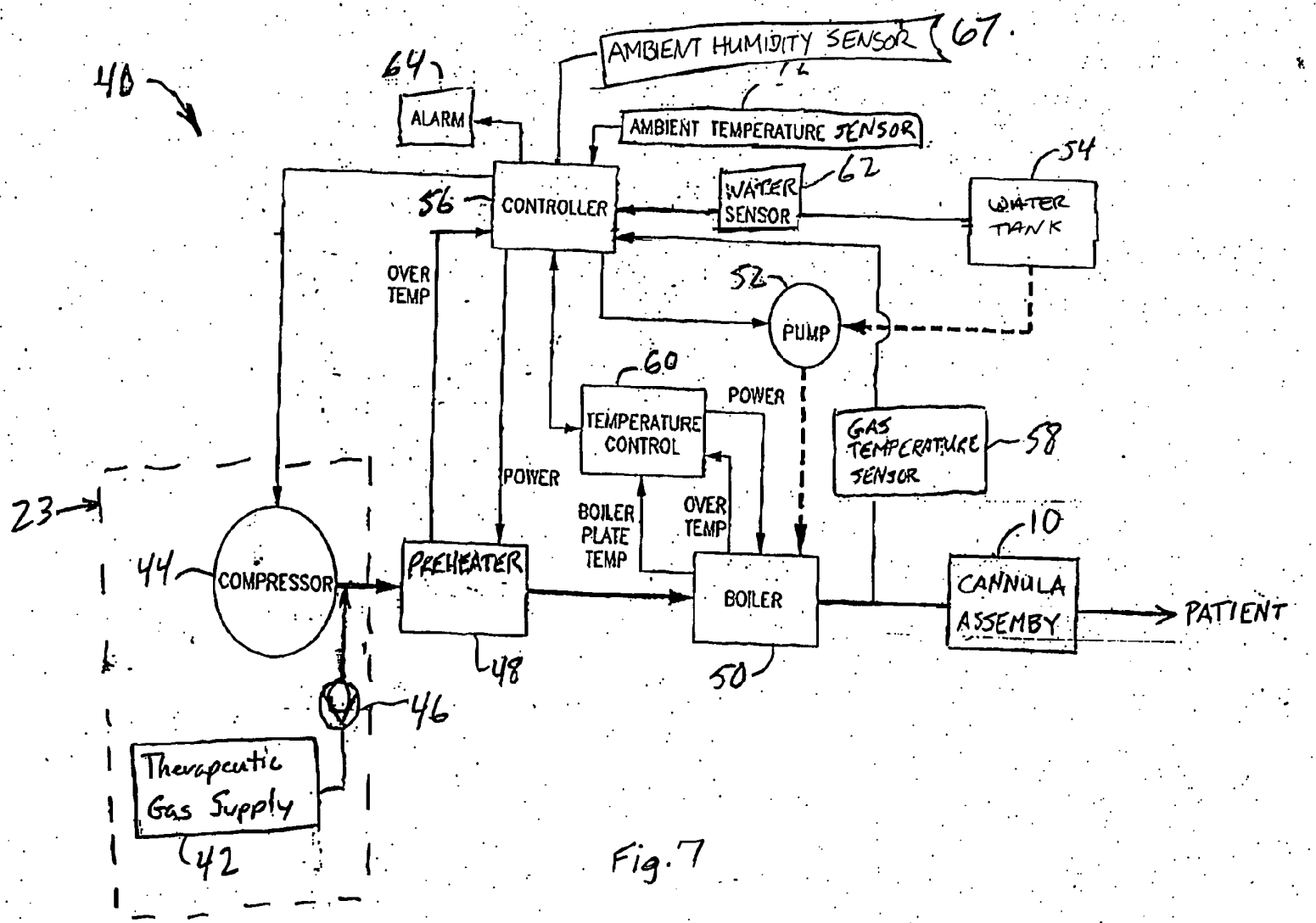

Fig. 7

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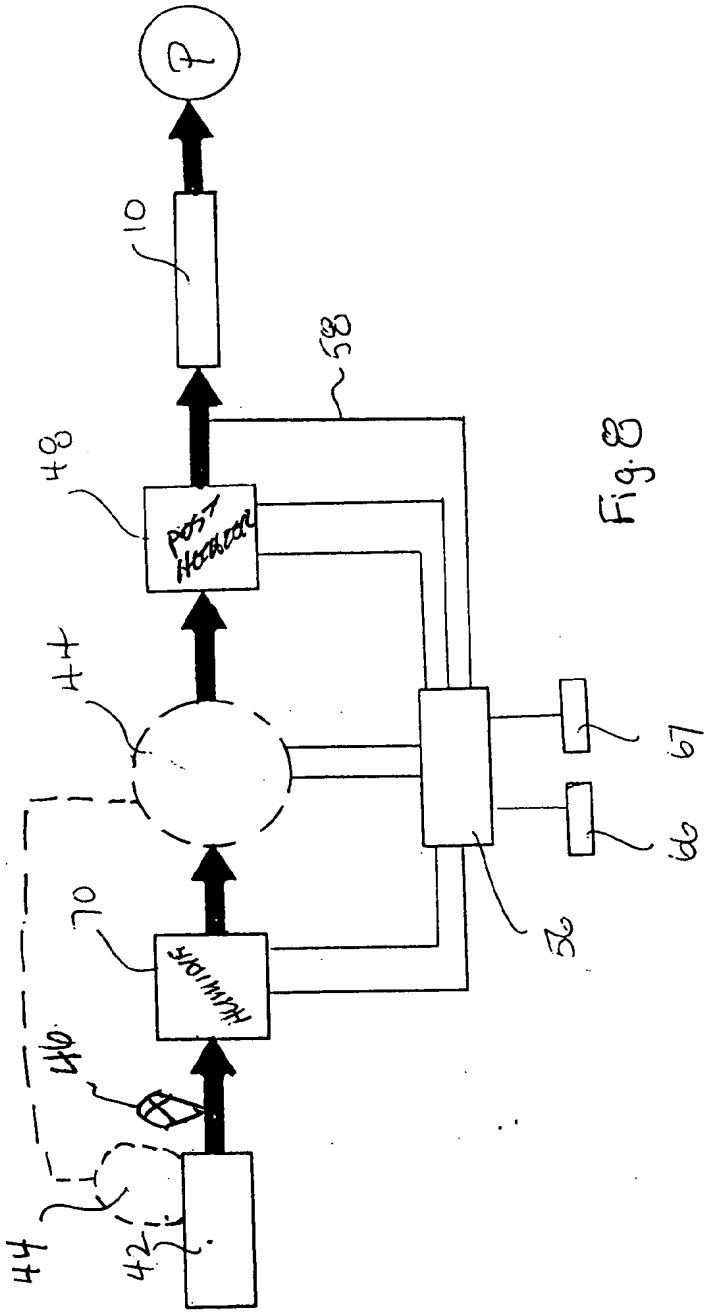

Fig. 3

Attorney's Docket No.: SALTER PR47USP1 ***PATENT***

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

☐ Application No.: ☐ Filed herewith

For: RESPIRATORY THERAPY SYSTEM INCLUDING A NASAL CANNULA ASSEMBLY

POWER OF ATTORNEY FOR PROVISIONAL APPLICATION

Each inventor, identified above and signing below, hereby appoints the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

(list name(s) and registration number(s))

Anthony G.M. Davis	**Registration No. 27,868**
Gary D. Clapp	**Registration No. 29,055**
Michael J. Bujold	**Registration No. 32,018**
Scott A. Daniels	**Registration No. 42,462**

Correspondence address: **Customer No. 020210**
Davis & Bujold, P. L. L. C.
Fourth Floor
500 North Commercial Street
Manchester, NH 03101-1151

Direct telephone calls to: Michael J. Bujold

Tel.No.: (603) 624-9220

(check the following item, if applicable)

☐ Each inventor, identified above and signing below, authorizes the above named attorney(s) and/or agents to accept and follow instructions from my/our representative(s).

	Inventor(s) Name	**Signature**
Date: -	James N. CURTI	
Date:	Peter W. SALTER	
Date:	James M. DAVENPORT	